USSN: 09/917,181 Atty Dkt: DURE-023

**PATENT** 

# **REMARKS**

# Status of the Claims

Claims 1, 2, 4, 6-14, 17-22, 24, 25, and 29-32 are currently pending in the application.

Claims 1 and 2 are amended with entry of this amendment.

Claims 14, 17 and 18 are canceled with entry of this amendment.

Claims 1, 2, 4, 6-13, 19-22, 24, 25, and 29-32 remain under consideration with entry of this amendment.

### Summary

Claims 1, 2, 4, 6-14, 17-22, 24, 25, and 29-32 are pending in the application and were examined in the Office Action dated 24 January 2005. Applicants note with appreciation that claims 24, 25 and 32 have been allowed, and further that claims 14, 17 and 31 are deemed allowable if amended to include all base limitations. However, the drawings remain objected to under 37 C.F.R. §1.83(a), and claims 1, 2, 4, 6-13, 18-22, 29 and 30 remain rejected on the following basis: (a) claims 1, 2, 4, 6-13, 18-20, 22 and 29 stand rejected under 35 U.S.C. §102(b) as unpatentable over U.S. Patent No. 5,087,244 to Wolinsky ("Wolinsky"); (b) claim 30 stands rejected under 35 U.S.C. §103(a) as unpatentable over Wolinsky; and (c) claim 21 stands rejected under 35 U.S.C. §103(a) as unpatentable over Wolinsky in view of U.S. Patent No. 6,113,915 to Aoki et al. ("Aoki"). Applicants respectfully traverse the remaining objections to the figures and the pending claim rejections for the following reasons.

#### Overview of the Amendment

Applicants, by way of this amendment, have canceled claims 14, 17 and 18, and have submitted amendments to claims 1 and 2 in order to bring the case into condition for allowance. More particularly, claims 14, 17 and 18 have been cancelled without prejudice and disclaimer. Cancellation of these claims is not in acquiescence to any

USSN: 09/917,181 Atty Dkt: DURE-023 PATENT

pending grounds of rejection, and applicants expressly reserve their right to bring the claims again in another related application.

Claims 1 and 2 have been amended to correct obvious typographical errors and to recite the invention with greater particularity. Specifically, claim 2 has been amended to correct a misspelling, and claim 1 has been amended to insert the limitations from claim 14 into the base claim (claim 1), that claim having been indicated as allowable. Support for the amendments to claims 1 and 2 can thus be found throughout the specification as originally filed, and in the claims as originally presented. Accordingly, no new matter has been added by way of these amendments to claims 1 and 2, and the entry thereof is respectfully requested.

# The Drawing Objections

The objection to Figures 8A and 8B under 37 C.F.R. §1.83(a) has been rendered moot by way of the cancellation of claims 17 and 18. Reconsideration and withdrawal of the objection is thus respectfully requested.

# The Rejection under 35 U.S.C. §102

Claims 1, 2, 4, 6-13, 18-20, 22 and 29 stand rejected under 35 U.S.C. §102(b) as unpatentable over Wolinsky. Applicants respectfully traverse the rejection in light of the present amendments to the claims.

In particular, applicants have moved the limitations from claim 14 into the base claim (claim 1). The Office has indicated that claim 14 would be allowable if rewritten in independent form to include all base limitations. Applicants' amendment to claim 1 has accomplished just that. Accordingly, claim 1 should be allowable. Furthermore, claims 2, 4, 6-13, 18-20, 22 and 29 all depend, either directly or indirectly from newly amended claim 1 and thus contain the same base limitations. Accordingly, claims 2, 4, 6-13, 18-20, 22 and 29 should also be allowable. Reconsideration and withdrawal of the rejection of claims 1, 2, 4, 6-13, 18-20, 22 and 29 under 35 U.S.C. §102(b) is thus respectfully requested.

USSN: 09/917,181 Atty Dkt: DURE-023 PATENT

# The Rejections under 35 U.S.C. §103

Claim 30 stands rejected under 35 U.S.C. §103(a) as obvious over Wolinsky. Applicants respectfully traverse the rejection in light of the present amendments to the claims.

As noted above, claim 1 as now amended recites a device comprising a diffuser element, wherein the diffuser element is substantially impermeable to biological fluids or components thereof. Claim 30 depends (indirectly) from claim 1 and thus contains this same base limitation. Under the Office's theory regarding the Wolinsky device, the microporous holes in the Wolinsky balloon would have to allow free flow of biological fluids into the catheter device in order to provide the dilution effect that the Office has argued. If, on the other hand, the Wolinsky device is constructed and operated as Wolinsky has actually described, the microporous holes in the Wolinsky balloon do not allow any inflow into the balloon, rather only drug will pass out from the device under the applied pressure. Accordingly, Wolinsky cannot destroy the patentability of claim 30. Reconsideration and withdrawal of the rejection of claim 30 under 35 U.S.C. §103(a) is thus earnestly solicited.

Claim 21 stands rejected under 35 U.S.C. §103(a) as obvious over Wolinsky in view of Aoki. Applicants respectfully traverse the rejection in light of the present amendments to the claims.

Here again, applicants note that claim 1 as now amended recites a device comprising a diffuser element, wherein the diffuser element is substantially impermeable to biological fluids or components thereof. Claim 21 depends (indirectly) from claim 1 and thus contains this same base limitation. Wolinsky clearly does not teach or suggest this feature as demonstrated above, and the secondary reference to Aoki is likewise silent on the issue. Accordingly, Wolinsky and Aoki, whether considered alone or in any conceivable combination, cannot destroy the patentability of claim 21. Reconsideration and withdrawal of the rejection of claim 21 under 35 U.S.C. §103(a) is thus earnestly solicited.

USSN: 09/917,181 Atty Dkt: DURE-023 PATENT

#### **CONCLUSION**

Applicants submit that the pending claims define an invention that is both novel and nonobvious over the cited art, and thus all claims are in condition for allowance. Acknowledgement of this by the Office in the form of an early allowance is thus respectfully requested. In addition, if the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, applicants invite the Examiner to contact the undersigned at (408) 777-4915.

No fees have been included with this submission. However, if the Commissioner determines that certain fees are indeed necessary, the Commissioner is hereby authorized to charge any fees associated with this submission to Deposit Account No. 50-1953.

Date: 25 April 2005

Respectfully submitted,

Thomas P. McCracken Registration No. 38,548

For and on behalf of DURECT CORPORATION 10240 Bubb Road

Cupertino, CA 95014 Phone: (408) 777-4915

Fax: (408) 777-3577